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(to be used for all correspondence after initial filing)

Application Number	09/936,841
Filing Date	March 1, 2002
First Named Inventor	Martin CALDWELL
Group Art Unit	3731
Examiner Name	Michael Thaler
Total Number of Pages in This Submission	40
Attorney Docket Number	741890-20

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Attorney Docket No. 741890-20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re PATENT application of	)	
Martin CALDWELL et al.	)	Confirmation No.: 1503
Application No. 09/936,841	)	Group Art Unit: 3731
Filed: March 1, 2002	)	Examiner: Michael Thaler
For: A SURGICAL ACCESS DEVICE	)	

APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
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Sir:

This Appeal Brief is submitted in support of the Notice of Appeal filed September 28, 2004, in furtherance of the Appeal Brief filed on November 29, 2004, and in response to the Notification of Non-Compliant Appeal Brief of February 9, 2005.

I. REAL PARTY IN INTEREST

Gaya Limited is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are presently no appeals or interferences known to the Appellants, the Appellants' representative, or the assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-4, and 7-18 are pending, as submitted in an Amendment After Final filed September 28, 2004 in response to the Final Office Action mailed May 24, 2004.

Claims 5-6 have been canceled. This Appeal is taken from the rejection of claims 1-4, and 7-18, as submitted in the Appendix herewith.

IV. STATUS OF AMENDMENTS

Further to the May 24, 2004 Final Office Action, Appellants submitted an Amendment After Final on September 28, 2004 amending claims 1, 3, 14, 15, 17, and 18 to reduce the issues for appeal and to overcome the Examiner's rejections. The Examiner indicated in the October 8, 2004 Advisory Action that the amendments to claims 1, 3, 14, 15, 17, and 18 would be entered for the purposes of Appeal. The pending claims are allowable over the applied references, as argued herein.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 relates to a surgical device (1) for use in minimally invasive surgery of the type using an inflated body cavity (2) accessible to a surgeon through an access port, defined by the device (1), surrounding an incision in a patient's body, the device (1) having a body cavity engagement means (5) for insertion into the incision to locate the device (1) in position, a fixing means (10) for attaching the device to a patient's skin, the fixing means including a proximal ring (6), a sleeve (4) connected between the body cavity engagement means and the fixing means, wherein the sleeve is adjustable by the positioning of the proximal ring so that the positioning of the proximal ring retracts the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision to define an access port and create a seal between the incision and sleeve, and a sealing means, at least one of mounted on the sleeve and operating on the sleeve, to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. (See, e.g., *Second Substitute Specification*, pages 3-5, paragraphs [0015]-[0024], and Figs. 1-7).

Independent claim 11 relates to a surgical device for use in minimally invasive surgery of the type using an inflated cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body, the device comprising a body cavity engagement means for insertion into the incision to locate the device in position, said body cavity engagement means including a distal ring, a fixing means for attaching the device to a patient's skin, said fixing means including a proximal ring, a sleeve connected between the body cavity engagement means and the fixing means, said sleeve having an adjustable length that shortens to cause said sleeve to apply outward pressure against the patient's body sufficient to retract the incision to define the access port, and one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring, to prevent substantial leakage of gas from the body cavity on inflation when in an operative position and formed to mold about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. (See, e.g., *Second Substitute Specification*, pages 3-5, paragraphs [0015]-[0024], and Figs. 1-7).

Independent claim 12 relates to a surgical device for use in minimally invasive surgery of the type using an inflated cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body, the device comprising a body cavity engagement means for insertion into the incision to locate the device in position, said body cavity engagement means including a distal ring, a fixing means for attaching the device to a patient's skin, said fixing means including a proximal ring, a sleeve connected between the body cavity engagement means and the fixing means, said sleeve having a length, wherein said proximal ring includes an adjustment means for adjusting the length of said sleeve to cause said sleeve to apply outward pressure against the patient's body sufficient to retract sides of the incision, and one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring, to prevent

substantial leakage of gas from the body cavity on inflation when in an operative position and formed to mold about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. (See, e.g., *Second Substitute Specification*, pages 3-5, paragraphs [0015]-[0024], and Figs. 1-7).

Accordingly, the invention advantageously relates to a surgical device having a sleeve connected between the body cavity engagement means and the fixing means, wherein the sleeve is adjustable by the positioning of the proximal ring so that the positioning of the proximal ring retracts the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision to define an access port and create a seal between the incision and sleeve. (see, e.g., *Second Substitute Specification*, page 2, paragraph [0006], and page 4, paragraph [0019]).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are as follows:

- Claims 9, 11, 12, 14, 15, 17, and 18 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.
- Claims 1-4 and 7-18 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over PCT Published Application WO 95/22289 to *Bonadio*.
- Claims 1-4 and 7-18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,649,550 to *Crook* in view of PCT Published Application WO 95/22289 to *Bonadio*.

VII. ARGUMENT

A. The Rejection of Claims 9, 11, 12, 14, 15, 17, and 18 as Failing to Comply With the Enablement Requirement of 35 U.S.C. §112, First Paragraph, Should Be REVERSED.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde,

242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? (See MPEP 2164.01) This standard is still the question to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though 35 U.S.C. §112 does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). In *Wands*, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. *In re Wands,* 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that "there was considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." *Id.*, 8 USPQ2d at 1407.

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was

filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The Final Office Action, dated May 24, 2004 continues to reject claims 9, 11, 12, 14, 15, 17, and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. More specifically, the final rejection alleges that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the rejection alleges that it is unclear from the specification and drawings how the external proximal valve is structured and how it is connected to proximal ring 6. In addition, the rejection alleges that since sleeve 4 is wrapped around proximal ring 6 as seen in figure 2, it is not seen how sleeve 4 can extend proximally to form the external proximal valve. Thus, it is alleged that if a structure other than sleeve 4 forms the external proximal valve (which is not disclosed), then it is unclear how this structure is connected to proximal ring 6.

In addition, the Advisory Action of October 8, 2004 alleges, for the first time, that, as to the rejection under 35 U.S.C. §112, first paragraph, it is not seen how a self-sealing valve such as the self-sealing valve shown at 18 in figures 1, 3, and 4 could function in the area external to the patient's abdominal wall 3 since it would be pulled radially outwardly by its connection to rings 6 and 5 and thus always be open. Furthermore, the Advisory Action alleges that it is not seen how a self-sealing valve such as the self-sealing valve shown at 18 in figures 1, 3, and 4 could function in the area external to the patient's abdominal wall 3 since it would be pulled radially outwardly by its connection to rings 6 and 5 and thus always be open.

Referring to the above rejections, Appellants contend that the specification and drawings clearly teach a person with ordinary skill in the art how to make and/or use the claimed invention for the following reasons.

First, the original specification specifically recites that the self-sealing valves 18 and 28 may be equally used as external proximal valves or as internal distal valves, see at least Figures 6, 7, and paragraphs [0025], [0028]. Therefore,

the structure of the external proximal valve is clearly taught. That is, the external proximal valve shown in Fig. 7 is attached adjacent to sleeve 4 in a similar manner to the internal distal valve shown in Figures 1-6. As taught by the specification, the external proximal valve is formed on a portion of the sleeve 4 extending from proximal ring 6 just as the internal distal valve shown in Figures 1-6 is formed on a portion of the sleeve 4 extending form distal ring 5. A person with ordinary skill in the art would understand based on the specification and drawings that a portion of sleeve 4 extends outwardly from proximal ring 6 while another portion of sleeve 4 wraps around proximal ring 6, see Examiner's statement on page 4 of the May 24, 2004 Final Office Action: "It would have been obvious to include a seal on the Crook device so that it too would have this advantage."

Moreover, the ability of the self-sealing valve 18 to function as an external proximal valve in the area external to the patient's abdominal wall is clear from the disclosure because self-sealing valve 18 incorporates elasticized filaments, which are biased toward a closed position or inoperative position. (See Second Substitute Specification, para. [0018] and Fig. 3). Thus, even though self-sealing valve 18 is attached to proximal ring 6, the elastic nature of self-sealing valve 18 causes self-sealing valve 18 to maintain a closed position regardless of the outward radial pull resulting from its connection to rings 5 and 6. Thus, it would have been clear to a person of ordinary skill in the art that the elastic properties of the self-sealing valve 18 could be utilized as an external proximal valve mounted adjacent to proximal ring 6.

The statement by the Examiner that "It would have been obvious to include a seal on the Crook device so that it too would have this advantage.", along with the teachings of the specification discussed above, constitute a *prima facie* admission that the claims 9, 11, 12, 14, 15, 17 and 18 are in-fact enabled.

The Appellants continue to assert that a person of ordinary skill in the art would understand that sleeve 4 can extend above proximal ring 6 just as it extends below the proximal ring 6 and extend upwardly to accommodate the mounting of the external proximal valve 18 based on the specification. A person of ordinary

skill in the art would understand that sleeve 4 may extend in both the direction of the proximal ring and outwardly to provide mounting of the external proximal valve since it is well known to form sleeves in a manner which allows different portions of the sleeve to extend in different directions for attachment of other components, as shown by the following patent documents:

U.S. Patent 5,640,977 (see Figure 2, elements, 13, 18b)
WO99/25268 (see Figure 8, elements 85, 80)
WO95/07056 (see Figure 3, elements 23,2)
WO01/08581 (see Figure 9, element 158, 152, Figure 10)

Thus, a person with ordinary skill in the art would understand that sleeve 4 could extend both around proximal ring 6 and a portion of the sleeve could also extend upwardly for mounting of the external proximal valve. Thus, it is believed that the specification, drawings and the knowledge of the person of ordinary of skill in the art is such that one skilled in the art would be able to make and/or use the invention as claimed.

Finally, the Examiner's setting forth a rejection under § 112 (first paragraph-enablement) and § 103, in which the Examiner asserts that a particular feature lacks enablement while at the same time stating that the same feature would have been obvious to one of ordinary skill in the prior art, constitutes an improper "squeeze". As can be seen from the attached USPTO training presentation entitled "The Squeeze", regarding combined "§ 112 (first paragraph-enablement) and § 103" rejections, the presentation clearly notes that such combination rejections (see *Evidence Appendix*, slides 6, 10, 15) are reserved for the most unusual situations where the claimed invention scope exceeds that of all the prior art, e.g., such as cures for all cancers. The Examiner's use of the "§ 112/§ 103 squeeze" in the instant final Office Action is inconsistent with the guidelines established by the USPTO's "The Squeeze" and further at MPEP Chapter 2164.04 regarding setting forth a *prima facie* case of lack of enablement.

Accordingly, since the § 112(1)-enablement rejection is improper in its analysis and understanding of the prior art at the time of the invention and the Applicants' disclosure and since the § 112(1)-enablement rejection is not

consistent with the USPTO procedures for setting forth a proper §112(1) enablement/§103 rejection, reversal of the rejection of claims 9, 11, 12, 14, 15, 17 and 18 under 35 U.S.C. 112, first paragraph, is respectfully requested.

B. The Rejection of Claims 1-4 and 7-18 Under 35 U.S.C. §102(b) as Anticipated By or, in the Alternative, Under 35 U.S.C. §103(a) as Obvious, Over Bonadio Should Be REVERSED.

If all claimed elements/steps are disclosed, expressly or inherently, in a single prior art reference, that reference is said to "anticipate" the claimed invention, thereby invalidating the claim(s) under 35 U.S.C. §102. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

The Supreme Court in *Graham v. John Deere*, 383 U.S. 1 at 18, 148 USPQ 459 at 167 (1996), set forth the basic test for patentability under 35 U.S.C. §103:

> Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unresolved need, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter to be patented.

Moreover, in *In re Ehrreich and Avery*, 200 USPQ 504, 509-510 (CCPA 1979), the Court of Customs and Patent Appeals further clarified the basic test set forth in *Graham v. John Deere*:

> We must not here consider a reference in a vacuum, but against the background of the other references of record which may disprove theories and speculations in the reference or reveal previously undiscovered or unappreciated problems. The question

> in a §103 case is what the references would collectively suggest to one of ordinary skill in the art. *In re Simon*, 461 F.2d 1387, 174 USPQ 114 (CCPA 1972). It is only by proceeding in this manner that we may fairly determine the scope and content of the prior art according to the mandate of *Graham v. John Deere*, 383 US 1, 17, 148 USPQ 459, 467 (1966)(Emphasis in original.)

Thus, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination," *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Further, analyzing the claimed invention as a whole in view of the prior art as a whole, one indicium of non-obviousness is a "teaching away" from the claimed invention by the prior art at the time the invention was made. See *U.S. v. Adams*, 148 USPQ 479 (1966). Essentially, teaching away from a claimed invention is a *per se* demonstration of lack of *prima facie* obviousness.

Where the prior art provides "only general guidance and is not specific as to the particular form of the invention or how to achieve it, [such a suggestion] may make an approach 'obvious to try,' but it does not make the invention obvious." *Ex parte Obukowicz*, 27 USPQ2d, 1063, 1065 (U.S. Patent and Trademark Office Board of Appeals and Interferences, 1992) and *In re O'Farrell*, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

Factors including unexpected results, new features, solution of a different problem, novel properties are all considerations in the determination of obviousness. These secondary considerations (objective evidence of non-obviousness), as outlined in *Graham v. John Deere*, must be evaluated before reaching an ultimate decision under 35 U.S.C. §103. Accordingly, the recognition and solution of a problem is considered indicia of non-obviousness. For example, as the Court of Appeals stated in *In re Sponnable*, "[A] patentable invention may lie in the discovery of a source of a problem even though the remedy may be obvious once the source of the problem is identified. This is *part* of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. §103." Donald S. Chisum, *Chisum on Patents* § 5.04[7][c][ii], at 5-506 (Rel. 51, 1994)

(quoting *In re Sponnable* 405 F.2d at 578, 585-86, 160 USPQ 237, 243-244 (CCPA 1969)(emphasis in original).

It should be noted that three criteria must be met to establish a *prima facie* case of obviousness. *M.P.E.P. §2143*. First, there must be some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. *In re Rhinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). Last, the prior art must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

The Appellants respectfully contend that the Examiner has failed to set forth a *prima facie* case of obviousness, since the applied references, taken alone or in combination, fail to teach, disclose or suggest all limitations recited in the claimed invention.

The Final Office Action, dated May 24, 2004 rejects claims 1-4 and 7-18 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bonadio (WO 95/22289). In addition, the Advisory Action of October 8, 2004 states that it is clear that pulling proximal ring 44 upwardly would pull the sleeve (the sleeve which passes within the incision) and bands 55 upwardly, causing the bands 55 to first abut the inner wall of the patient's cavity and then to pull the inner wall, along with the incision, upwardly, thus meeting the phrase "to cause the sleeve to apply outward pressure against the patient's body to retract the incision" in claim 1. Similarly, the Advisory Action alleges that the proximal ring 44 is inherently capable of being manually grasped by a surgeon and pulled upwardly prior to its attachment to the skin by the adhesive. However, Applicants contend that Bonadio does not render the present invention as recited in independent claims 1, 11 and 12 anticipated or obvious for the following reasons.

Bonadio discloses a body cavity engagement means, a sleeve and a sealing means 102. The Examiner states that Bonadio further includes a proximal ring 44

which if pulled upwardly would inherently cause the sleeve to apply outward pressure against the patient's body to retract the incision. However, this statement by the Examiner is simply not factually accurate and completely contrary to the teachings of Bonadio in that upward movement of proximal ring or flange 44 is not explicitly or implicitly taught by Bonadio and, further, would not cause the sleeve to apply outward pressure against the patient's body to retract the incision. Bonadio nowhere suggests such an interpretation and, as a practical matter, upward movement of flange 44 would merely result in the movement of the sleeve upwardly through the incision and out of the cavity and cause the bands 55 to abut the inner wall of the patient's body. The structure of the Bonadio design simply does not permit an outward pressure against the patient's body sufficient to retract the incision, see page 22, line 2-7, where it is stated that inflation of the cavity results in leakage of gas between the incision and the sleeve. Further, Bonadio clearly teaches that the upper seal, e.g., 44, provides the sealing necessary such as by being adhesively attached to the skin, see page 5, lines 19-23, page 12, lines 5-18, and page 21, lines 26-33). Such a teaching would not implicitly (inherently) teach one of ordinary skill in the art that "pulling" as stated would be intended or "necessarily present" as is required for "inherency" to exist, see the guidelines set forth in MPEP Chapter 2112.

Further, MPEP Chapter 2143.01 clearly states that a proposed modification of a reference to include a feature or functionality which is contrary to the purpose or function stated in a prior art reference and/or which would render the teachings of the prior art reference unsatisfactory for its intended purpose does not provide a proper suggestion/motivation to make the proposed change. Since Bonadio does not explicitly state (or remotely suggest) such a retraction and nowhere discusses any form of retraction by (upward) movement of the flange 44 (to the contrary, flange 44 remains in place on the skin to form a seal), the "inherent" movement of the flange (such as during positioning of the flange adjacent the incision) would not as a technical and practical matter result in outward pressure to retract or open the incision. Bonadio is simply an access port device for permitting access to a

patient's body cavity but does not function as a retractor for prying an incision open using outward pressure as presently claimed. Thus, Bonadio does not teach or even remotely suggest an inherent capability of a sleeve which is adjustable by the positioning of a proximal ring so that the positioning of the proximal ring retracts the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision to define an access port and create a seal between the incision and sleeve as specifically recited in independent claim 1.

Nor does Bonadio anywhere teach or suggest the sleeve having an adjustable length that shortens (claim 11) or an adjustment means for adjusting the length of a sleeve (claim 12) to cause the sleeve to apply outward pressure against the patient's body sufficient to retract the incision. Bonadio is completely devoid of any teaching of an "adjustable" length sleeve. Moreover, there is certainly no suggestion or motivation in Bonadio to modify the Bonadio teaching so as to provide a sleeve which is adjustable by the positioning of the proximal ring so as to retract the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision. Nor is there any suggestion or motivation to modify the Bonadio teaching to include a sleeve having an adjustable length that shortens to cause the sleeve to apply outward pressure to retract the incision.

Moreover, as to claims 13-15, the Examiner asserts that the sealing means is a feature of means 102 in Bonadio yet then states that the arcuate bands 55 in Bonadio correspond to the elasticized filaments. However, claims 13-15 specifically require the sealing means (claim 13), or the external or internal sealing valve (claims 14 and 15), to be a self-sealing valve formed of elasticized filaments. Bonadio does not state or even remotely suggest that sealing means 102 includes elasticized filaments. Therefore, Bonadio does not anticipate or render obvious the present invention as recited in dependent claims 13-15. Likewise, claims 16-18 are not anticipated nor rendered obvious by Bonadio since the sealing means 102 in Bonadio does not include a self-sealing spring valve much less a tensioned member mounted on the sleeve as the spring valve. Thus, dependent claims 16-18 are also allowable over Bonadio.

In summary, the Bonadio reference simply does not (explicitly or implicitly) teach, disclose, suggest or otherwise motivate a person of ordinary skill in the art to incorporate the features of the invention as claimed in independent claims 1, 11 and 12. Importantly, the Bonadio access device does not and could not inherently operate in the manner described by the Examiner to retract the incision, and, further, the teachings therein are in fact contrary to the device of claims 1, 11 and 12. Upward movement (as suggested by the Examiner) of flange 44 will not apply outward pressure against the patient's body to retract the incision and the flat adhesive surface provided on flange 44 fundamentally foregoes rotation of the flange while maintaining the adhesive surface exposed for connection as required by the Bonadio teaching. Bonadio simply fails to teach a sleeve which functions in any manner to retract on the sides of an incision, and certainly fails to teach the manner of retraction recited in independent claims 1, 11 and 12 of the present application. Thus, Bonadio neither anticipates nor renders obvious the present invention as recited in independent claims 1, 11 and 12 (or dependent claims 2-4, 7-10, 13-18).

Accordingly, since the applied references fail to teach, suggest or disclose each and every claimed feature, the applied references can not anticipate nor render obvious the claimed invention. Thus, reversal of the rejection of claims 1-4, 7-18 under 35 U.S.C. 102(b) or under 35 U.S.C. 103(a) is respectfully requested.

C. The Rejection of Claims 1-4 and 7-18 as Being Unpatentable under 35 U.S.C. §103(b) in view of PCT Published Application WO 95/22289 to *Bonadio* and U.S. Patent No. 5,649,550 to *Crook* Should Be REVERSED.

Claims 1-4 and 7-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Crook '550 in view of Bonadio. Applicants contend that the combination of Crook and Bonadio fails to render the present invention, as recited in independent claims 1, 11 and 12, obvious for the following reasons.

The present invention as recited in independent claims 1, 11 and 12 provides a surgical access device which permits effective retraction of an incision by adjusting a sleeve to provide outward pressure to a patient's body at the incision to define an access port in combination with a sealing means or sealing valve which prevents substantial leakage of gas from the cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. Admittedly, the Crook reference discloses a surgical retractor incorporating a sleeve. However, Crook fails to disclose any form or means for sealing around a hand or instrument extending through the retractor; while Bonadio does not suggest a retractor for applying outward pressure to the sides of the incision to retract the incision. Note the structure of Bonadio, in order to form a proper seal requires that the flange 44, which is part of the external sealing sleeve 40, remain fixed adjacent the patient's skin in the area of the incision. The Applicants assert that to combine the teachings of Bonadio with those of Crock would require significant reengineering of the teachings of Bonadio sealing structure to accommodate the roll down sleeve structure of Crook so as to remain fixed adjacent the patient skin.

In the Final Office Action of May 24, 2004, the Examiner states that it would be obvious to include a seal on the Crook device so that it would have an advantage of insuring the gas does not escape the patient. However, the Examiner is merely stating an advantage of the Bonadio valve but such a statement does not provide motivation for combining the valve with a retraction device. Both Crook and Bonadio each have independent advantages in that Crook advantageously retracts an incision while Bonadio advantageously provides a sealing means in the access port. It is quite apparent that using hindsight, with full knowledge of Applicants' invention, the Examiner is plucking these two distinct teachings from the vast prior art to claim obviousness. However, neither Bonadio nor Crook suggested in any way the application of one device to the other. Without some motivation to actually combine the references, a person of ordinary skill in the art

would not turn to these distinct teachings and combine the retractor of Crook and the sealing means of Bonadio. This lack of motivation is especially evident in view of the fact that Bonadio provides an access port through the incision without any mention whatsoever of some form of retraction to seal the sleeve to the sides of the incision. Moreover, Bonadio certainly fails to suggest that some form of outward pressure type retraction is desirable (much less a sleeve that is adjustable or has an adjustable length to apply outward pressure against the patient's body as presently claimed). Thus, it is respectfully requested that the combination of Crook and Bonadio does not render the present invention as recited in independent claims 1, 11 and 12 obvious.

Thus, Appellants respectfully submit that the applied references fail to teach, suggest or disclose at least the above features. Thus, the applied references can not anticipate, nor render obvious, the claimed invention. Accordingly, reversal of the rejection of claims 1-4 and 7-18 under 35 U.S.C. 103(a) is respectfully requested.

Thus, the prior art fails to provide a surgical access device which permits effective retraction of an incision by adjusting a sleeve to provide outward pressure to a patient's body at the incision to define an access port in combination with a sealing means or sealing valve which prevents substantial leakage of gas from the cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position. For example, the prior art does not teach surgical access device having an adjustable sleeve to provide outward pressure against the patient's body to retract an incision, in particular, a surgical access device with a sleeve having an adjustable length that can be adjusted to cause the sleeve to apply outward pressure to retract the incision. (see, e.g., *Second Substitute Specification*, page 2, paragraph [0006], and page 4, paragraph [0019]).

Accordingly, for at least the reasons stated above, it is believed that the specification, drawings and the knowledge of the person of ordinary of skill in the art is such that one skilled in the art would be able to make and/or use the invention as claimed. In addition, because the applied references fail to teach,

suggest or disclose, either expressly or inherently, either alone or in combination, each and every feature of the claimed invention, the applied references cannot anticipate the claimed invention. Furthermore, since the applied references do not teach or suggest each and every feature of the claimed invention, the claimed invention would not have been obvious to one of ordinary skill in the art based on the teachings of the applied references.

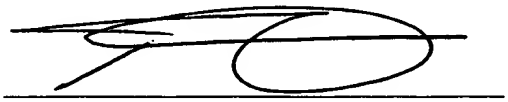
Therefore, at least for the foregoing reasons, the applied references do not anticipate, nor can render obvious, the claimed invention. Accordingly, the rejections under 35 U.S.C. §102 and 35 U.S.C. §103 should be reversed.

In addition, because the specification, drawings and the knowledge of the person of ordinary of skill in the art is such that one skilled in the art would be able to make and/or use the invention as claimed, the rejections under 35 U.S.C. §112 should also be reversed.

For all of the reasons discussed above, it is respectfully submitted that all claims 1-4, and 7-18 define patentable subject matter under 35 U.S.C. §102, 35 U.S.C. §103, and 35 U.S.C. §112. Accordingly, Appellants respectfully request this Honorable Board to reverse the rejections of claims 1-4, and 7-18.

Respectfully submitted,

NIXON PEABODY, LLP



Date: March 1, 2005

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VIII. CLAIMS APPENDIX

1. A surgical device (1) for use in minimally invasive surgery of the type using an inflated body cavity (2) accessible to a surgeon through an access port, defined by the device (1), surrounding an incision in a patient's body, the device (1) having:

body cavity engagement means (5) for insertion into the incision to locate the device (1) in position;

fixing means (10) for attaching the device to a patient's skin, the fixing means including a proximal ring (6);

a sleeve (4) connected between the body cavity engagement means and the fixing means, wherein the sleeve is adjustable by the positioning of the proximal ring so that the positioning of the proximal ring retracts the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision to define an access port and create a seal between the incision and sleeve; and

sealing means, at least one of mounted on the sleeve and operating on the sleeve, to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

2. The surgical device of claim 1 in which the body cavity engagement means (5) is provided by a distal ring (5) formed for insertion into the incision.

3. The surgical device of claim 2, in which the sealing means includes a self-sealing valve mounted on the sleeve.

4. The surgical device of claim 1, further including a connector ring (7) mounted adjacent said proximal ring.

5.-6. (Canceled)

7. The surgical device of claim 2, in which the fixing means (6) incorporates adjustment means for modifying the length of the sleeve, so as to ensure that the fixing means (6) and the distal ring (5) may be brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device (1) is firmly mounted in position.

8. The surgical device of claim 1, in which the sleeve is made of an elastomer material, whereby insertion of the distal ring into an incision stretches the elastomer material causing tension between the distal ring and proximal ring.

9. The surgical device of claim 1, wherein said sealing means is an external proximal valve mounted adjacent to said proximal ring.

10. The surgical device of claim 1, wherein said sealing means is an internal distal valve.

11. A surgical device for use in minimally invasive surgery of the type using an inflated cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body, the device comprising:

body cavity engagement means for insertion into the incision to locate the device in position, said body cavity engagement means including a distal ring;

fixing means for attaching the device to a patient's skin, said fixing means including a proximal ring;

a sleeve connected between the body cavity engagement means and the fixing means, said sleeve having an adjustable length that shortens to cause

said sleeve to apply outward pressure against the patient's body sufficient to retract the incision to define the access port; and

one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring, to prevent substantial leakage of gas from the body cavity on inflation when in an operative position and formed to mold about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

12. A surgical device for use in minimally invasive surgery of the type using an inflated cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body, the device comprising:

body cavity engagement means for insertion into the incision to locate the device in position, said body cavity engagement means including a distal ring;

fixing means for attaching the device to a patient's skin, said fixing means including a proximal ring;

a sleeve connected between the body cavity engagement means and the fixing means, said sleeve having a length;

wherein said proximal ring includes an adjustment means for adjusting the length of said sleeve to cause said sleeve to apply outward pressure against the patient's body sufficient to retract sides of the incision; and

one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring, to prevent substantial leakage of gas from the body cavity on inflation when in an operative position and formed to mold about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

13. The surgical device of claim 1, wherein said sealing means is a self-sealing valve formed of elasticized filaments.

14. The surgical device of claim 11, wherein said one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring is a self-sealing valve formed of elasticized filaments.

15. The surgical device of claim 12, wherein said one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring is a self-sealing valve formed of elasticized filaments.

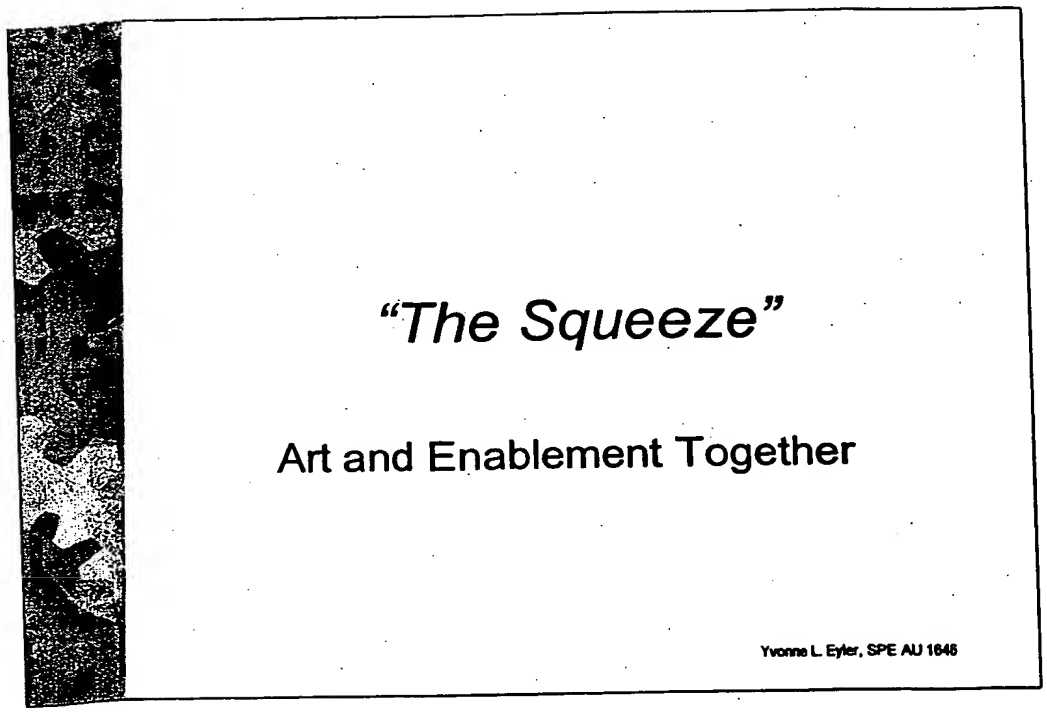
16. The surgical device of claim 1, wherein said sealing means is a self-sealing spring valve including a tensioned member mounted on the sleeve.

17. The surgical device of claim 11, wherein said one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring is a self-sealing spring valve including a tensioned member mounted on the sleeve.

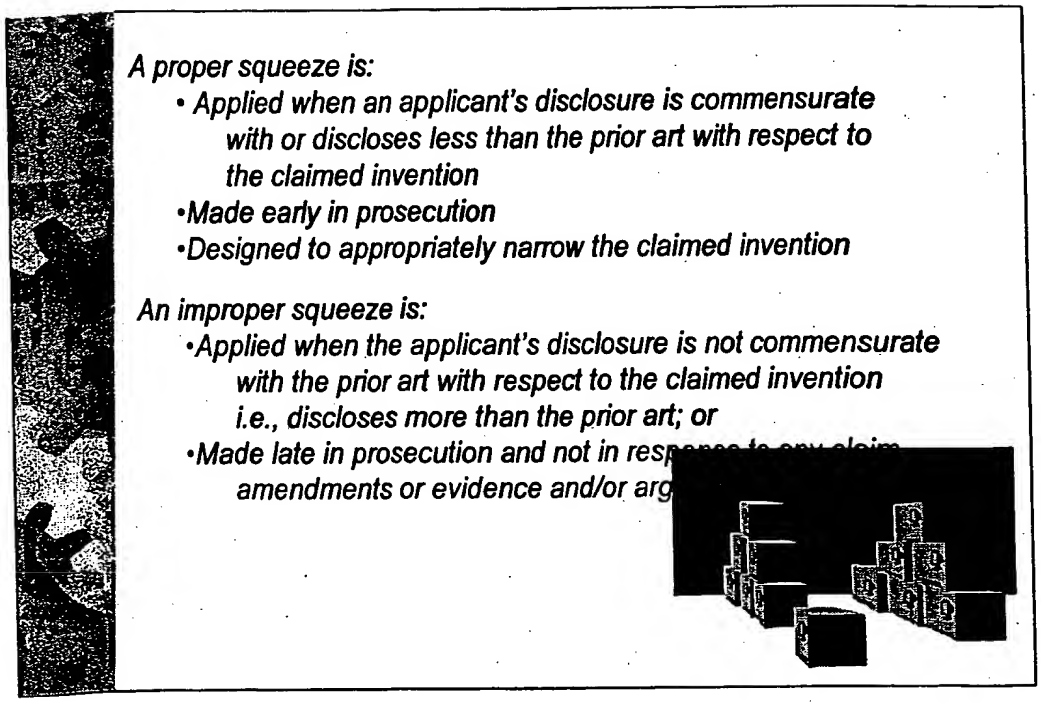
18. The surgical device of claim 12, wherein said one of an external proximal sealing valve mounted adjacent to said proximal ring and an internal distal sealing valve mounted adjacent to said distal ring is a self-sealing spring valve including a tensioned member mounted on the sleeve.

IX. EVIDENCE APPENDIX

Please see the attached copy of a PTO Lecture entitled "The Squeeze" (17 pages). This document was originally submitted in conjunction with the Amendment After Final filed September 28, 2004 in support of arguments presented therein.



When is it appropriate to apply both an art rejection and an enablement rejection?



Today I'll talk about examples of both improper and proper squeeze, beginning with improper combinations

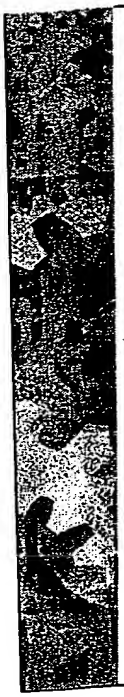
Lack of Enablement and Art-

Specification Discloses More Than Prior Art

- Claim 1: A method of treating ORANGE syndrome comprising administering to a patient an antibody that decreases the level of FL polypeptides associated with fluid retention.

The Specification Discloses

- Increased levels of FL polypeptides in ORANGE patients
- Cells overexpressing FL *in vitro* show increased permeability
- Mice overexpressing FL show increased fluid retention which is alleviated by administration of antibodies to FL.



The Prior Art Teaches:

- Increased levels of FL polypeptide is diagnostic of ORANGE syndrome.

An Improper "Squeeze"

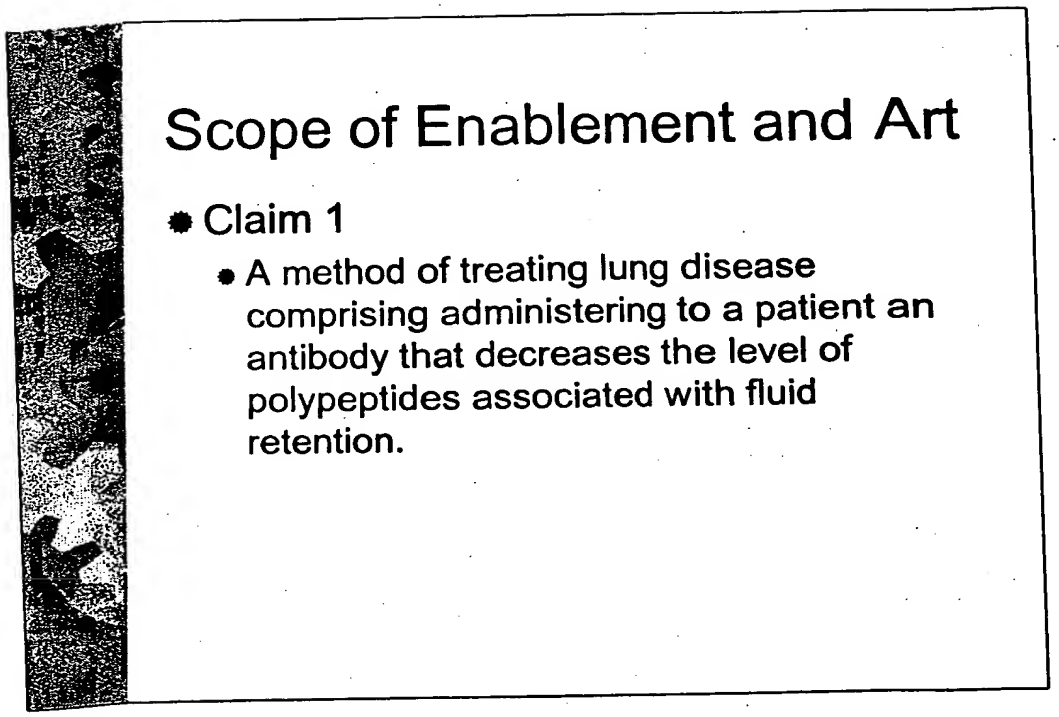
- The examiner rejects claim 1 under 35 U.S.C 112 first paragraph because no working examples of reduction of fluid retention in ORANGE patients are present and further questions the applicability of mouse models in general.
- The examiner also rejects claim 1 under 35 U.S.C. 103 over the art, stating that it would be obvious to administer antibodies to reduce the levels of FL polypeptide in ORANGE patients.

These rejections are examples of inconsistent rejections that box applicant in inappropriately. The invention is simultaneously rejected as not enabled and obvious when there are clear differences between the teachings of the specification and the prior art.

Make it clear that;

if the examiner can support a prima facie case of lack of enablement, an art rejection would be inappropriate because the reference, which is less comprehensive than the disclosure, does not provide an enabling disclosure.

if the reference is sufficient to establish a prima facie case of obviousness (and thus provides an enabling disclosure, considered alone or in combination with the knowledge in the prior art), then the application provides an enabling disclosure.



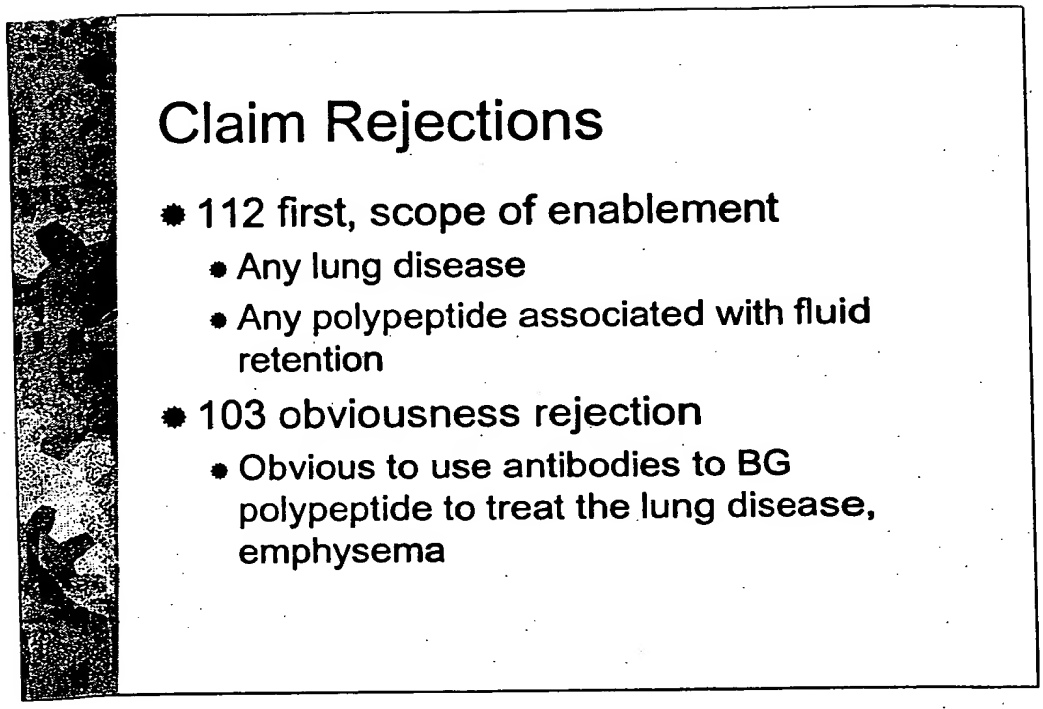
Now lets look at some examples of a proper squeeze.

The Specification Discloses

- Increased levels of a novel TP polypeptide (SEQ ID NO: 2) are associated with rockin' pneumonia virus and correlative with fluid retention in the lungs of pneumonia patients.
- Administration of antibodies to SEQ ID NO: 2 to pneumonia patients decreased viral load and fluid retention.

The Prior Art Teaches:

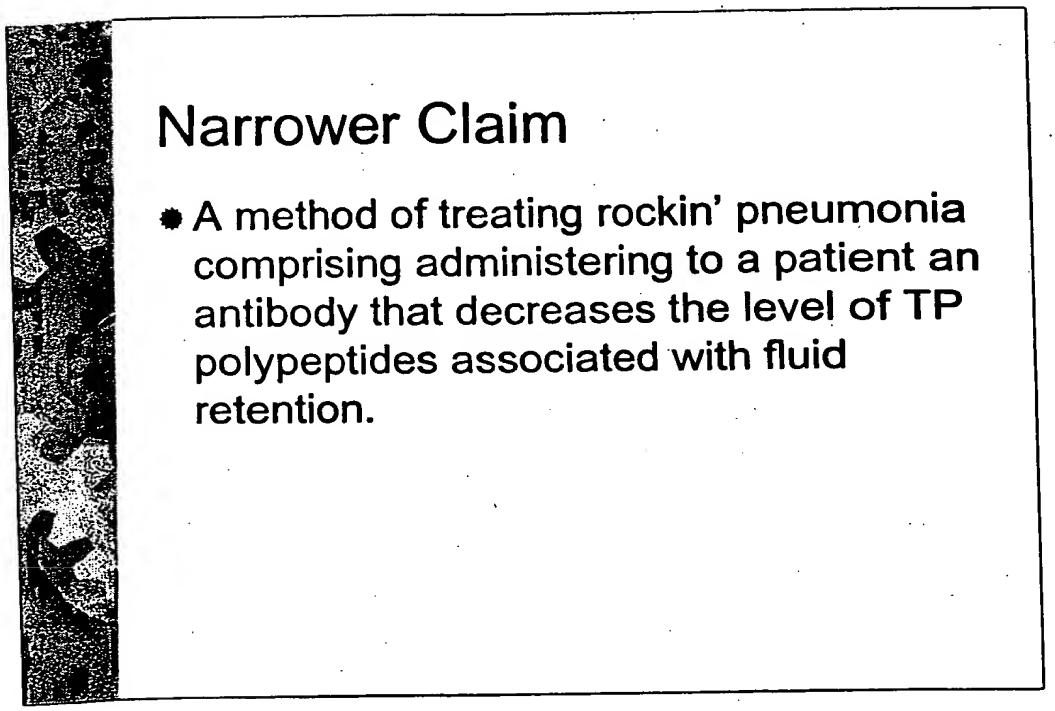
- Polypeptide BG is elevated in emphysema and increases fluid levels in the lungs of emphysema patients.
- Administration of antibodies to BG polypeptide decreases permeability and fluid leakage in cell from emphysema patients.
- Suggests that antibodies to BG may be useful in treating emphysema.



The specifiation does not enable treatment of lung diseases other than rockin' pneumonia and reduction of any polypeptide other than TP

The prior art enables treatment of emphysema by reduction of a polypeptide, BG

Therefore, 2 diseases treatments are clearly enabled, rockin' pneumonia by reduction of TP and emphysema by reduction of BG



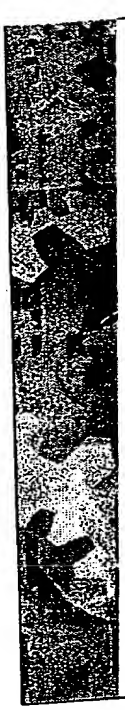
The specification fully supports this claim

The prior art does not teach or suggest this claim

Lack of Enablement and Art-

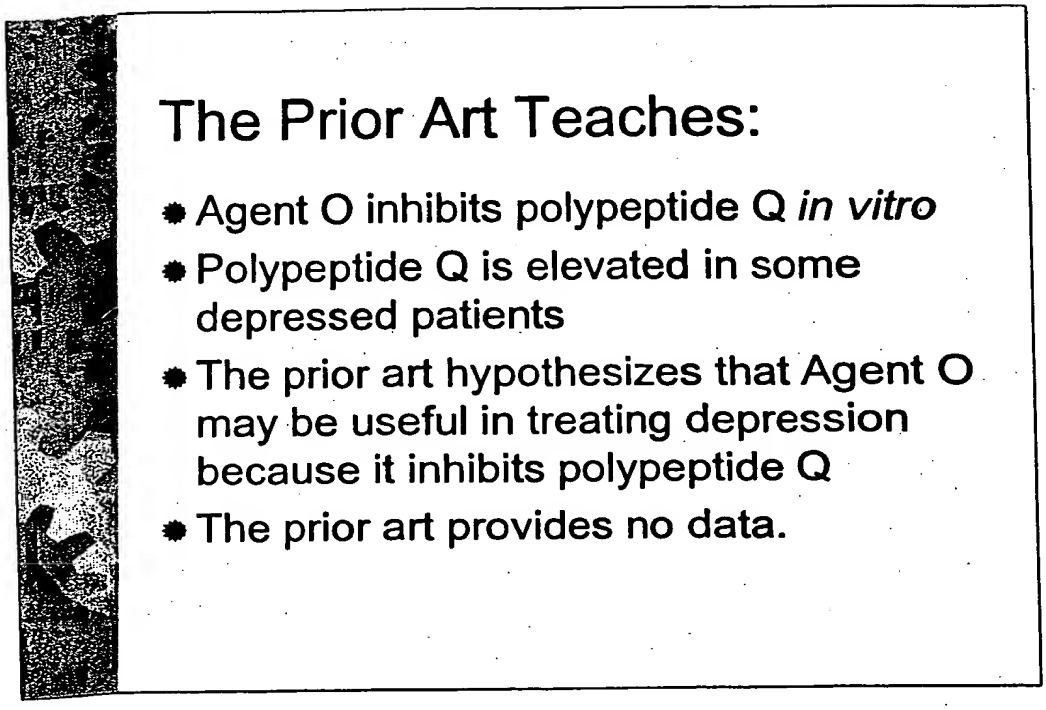
Specification Commensurate with Prior Art

- Claim 1: A method of treating depression comprising administering agent O.



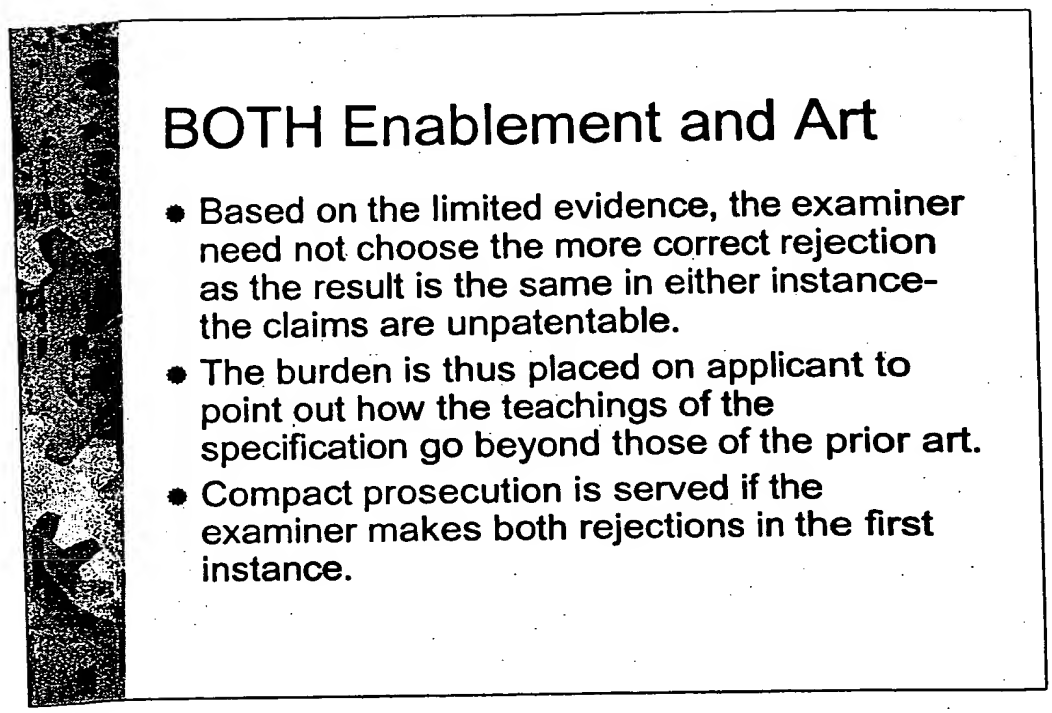
The Specification Discloses

- The specification has no working examples
- The specification suggests that agent O may be useful in treating depression because it inhibits a polypeptide Q whose level is elevated in some depressed patients.


The Prior Art Teaches:
Agent O inhibits polypeptide Q *in vitro*
Polypeptide Q is elevated in some depressed patients
The prior art hypothesizes that Agent O may be useful in treating depression because it inhibits polypeptide Q
The prior art provides no data.

Enablement and/or Art?

- In circumstances such as this, where the specification does not appear to add anything not taught by the prior art, the examiner may not have sufficient evidence to determine which rejection is more appropriate, i.e., the art rejection or the enablement rejection. If the specification is enabling, so is the prior art reference, and vice versa.



Compact prosecution is served because if only the prior art rejection were made, if applicant can show that the reference is not enabling and is based on an "obvious to try" standard, then the examiner would be in the position of having to drop the art rejection, only to reopen prosecution to make the enablement rejection and give applicant the opportunity to point out how the teachings of the specification go beyond those of the prior art...and vice versa.

Questions?